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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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William J. Carroll

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BLANK ROME LLP

600 NEW HAMPSHIRE AVENUE, NW

WASHINGTON, DC 20037

EXAMINER

STOKLOSA, JOSEPH A

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/761,424	Applicant(s) CARROLL ET AL.	
	Examiner JOSEPH STOKLOSA	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 15-19, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 15-19, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/14/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 1-5, 7-8, 15-19, and 21-22 are objected to because of the following informalities: Claim 1 and 15 contain the limitation that the electrodes are "implanted to the dura matter" and sound as if there is a connection to the body. Appropriate correction is required, such as "adapted to be implanted to the dura matter."

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-8 and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US 2001/0031999) in view of Reiss (US 5,324,317) and in view of Holsheimer et al. (US 5,643,330). In regards to claims 1 and 15, Carter discloses an

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electrical stimulator for the treatment of pain (see for example paragraphs 2, 57, 58, Figure 2), comprising an interferential current generator that is capable of generating interferential alternating current output (see for example paragraphs 12 and 13), by using common sine wave generators (see for example paragraphs 63 and 77, and Figure 8), with a base frequency of at least 1 KHz (see for example paragraph 12) that are capable of being positioned at locations proximate to a patient's spinal cord and other locations (see for example paragraphs 36, 38, 41, 53 and 58). Further in regards to claims 1; Carter discloses a beat frequency, which is defined as difference between the feed signals (paragraph 36), however; Carter does not specifically disclose the use of at least two pair of implantable electrodes.

5. Reiss teaches that it is known to use at least two pairs of electrodes in interferential current treatments as set forth in Col. 2, line 27-38, for providing the predictable result providing optimization of the stimulation at the center.

6. Holsheimer discloses an interferential spinal cord stimulation system with implantable electrodes for providing the predictable results of decreasing the power consumption of the device by placing the electrode on the actual stimulation site, as well as ensuring proper placement of the electrodes in chronic stimulation patients.

7. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Carter with use of at least two pairs of electrodes, as taught by Reiss, and implantable electrodes positioned on the dura matter between the epidural space, as taught by Holsheimer, since such modifications would provide the predictable results of optimization of the stimulation at

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the center and decreasing the power consumption of the device by placing the electrode on the actual stimulation site, as well as ensuring proper placement of the electrodes in chronic stimulation patients.

8. In regards to claims 2 and 16, Examiner takes the position that the Carter reference teaches of a pulse generator that generates digital signal pulses and the use of a digital signal processor (see for example paragraphs 63 and 75). Or in the alternative, Examiner take the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Carter to include a pulse generator that generates digital signal pulses and a digital signal processor, since these components are well known in the art to provide efficient and effective stimulation.

9. In regards to claim 3 and 17, Carter teaches of the use of pulse generator that generates digital signals (see for example paragraphs 63 and 75). Or in the alternative, similar to claim 2, Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Carter to include a pulse generator that generates digital signals, since it is well known in the art that digital signals can be used to provide efficient and effective stimulation. Further, Carter does not specifically teach of the use of a field-programmable gate array; however, Examiner takes the position that the use of field-programmable gate arrays are well known in the art and it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as

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taught by Carter to include a field programmable gate array, since field programmable gate arrays are known in the art to enhance digital signals.

10. In regards to claim 4 and 18, Carter teaches of the use of a beat frequency that does not exceed 250 Hz (see for example paragraph 36).

11. With regard to claims 5-7 and 19-21, Carter in view Reiss discloses the claimed invention except for stimulation voltage and pulse width parameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Carter in view of Reiss with a voltage of 11 volts maximum and a pulse width of 210 microseconds, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum workable ranges involves only routine skill in the art [*In re Aller*, 105 USPQ 233] and/or since it has been held that a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ (Please see MPEP 2144.05).

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12. In regards to claim 8 and 22, Carter does not specifically teach of the use of two quadripolar lead; however, Examiner takes the position that the use of quadripolar leads are well known in the art and it would have been obvious to one having ordinary skill in the art to modify the system as taught by Carter to include quadripolar leads, since quadripolar are well known in the art to provide effective and efficient stimulation.

Response to Amendment

13. The declaration under 37 CFR 1.132 filed 11/14/2008 is insufficient to overcome the rejection of claims 1 and 15 based upon Carter in view of Reiss and in view of Holsheimer as set forth in the last Office action because:

14. It states that the claimed subject matter solved a problem that was long standing in the art. However, there is no showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references; they would still be unable to solve the problem. See MPEP § 716.04. In Applicant's declaration paragraph 6 references other studies but fails to provide evidence from the referenced other studies (Page 3, line 7).

Applicant notes in paragraph 7 that up to now the only demonstrated results of the procedures have been short term effects. Examiner considers a short term effect to also be relieving intractable pain, as the declaration and claims are directed to relieving intractable pain and not long term intractable pain.

15. It include(s) statements which amount to an affirmation that the claimed subject matter functions as it was intended to function (e.g. paragraph 12). This is not relevant

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to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716.

16. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Response to Arguments

17. Applicant's arguments filed 11/14/2008 have been fully considered but they are not persuasive.

18. Applicant argues that Carter fails to teach the use of a beat frequency. Examiner respectfully disagrees. Carter is explicit in disclosing two separate channels with different sinusoidal signals of differing frequency (e.g. paragraph 12). Carter also acknowledges that transmission of the signal through the body of the patient will alter the different signals, in combination with the differing signals, and the overall affect is a beat frequency (e.g. paragraph 36). While operational differences may exist between the invention as disclosed by Applicant and Carter, Examiner must consider Carter's disclosure of a beat frequency to sufficiently meet the claimed limitations of a beat frequency, as a claim must be given its broadest reasonable interpretation.

19. Applicant argues that the beat frequency is not created at the dura matter of an epidural space. Examiner considers that the claim as written only requires the beat frequency to be formed proximate to the subject's spinal cord.

Conclusion

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

Joseph Stoklosa
Examiner
Art Unit 3762

/Joseph Stoklosa/
Examiner, Art Unit 3762
2/4/2009